

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Cordia Myxa on prevention the effect of mouthwashes fruits of stomatitis (mouth sores) in patients receiving chemotherapy

Protocol summary

Study aim

Cordia Myxa on prevention the effect of mouthwashes fruits of stomatitis (mouth sores) in patients receiving chemotherapy

Design

randomized, double-blind, controlled clinical trial

Settings and conduct

Then the researcher attended in the hematology wards of Shafa And Baghai2 Hospitals and informed writing consent was obtained from patients who were willing to participate in the study. Patients were admitted to the hospital one day before chemotherapy

Participants/Inclusion and exclusion criteria

Patients undergoing chemotherapy in the oncology departments of Shafa and Baghaee 2 Hospitals/Inclusion criteria:Age over 18 years, Acute leukemia under periodic chemotherapy in the induction and intensification phases,Complete alertness-Exclusion criteria:Asthma, allergies, and other sensitivity diseases, Simultaneous chemotherapy and radiotherapy, Development of a systemic infection during the study

Intervention groups

After which, correct use of mouthwash was taught, so that the mouth was washed for one minute with 30 drops of 5% formulation of lasura (Cordia myxa) fruit mucilage poured in 20 mL water; then the mouthwash was spat out, followed by not eating for up to 1 hour. After training, the treatment and the control groups were given lasura mouthwash and sterile water (with the same flavor and taste), respectively, in a glass that has a dropper.

Main outcome variables

Cordia Myxa: prevention: stomatitis: chemotherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180511039610N2**

Registration date: **2018-10-24, 1397/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-24, 1397/08/02**

Update count: **0**

Registration date

2018-10-24, 1397/08/02

Registrant information

Name

Bayan saberipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 6702

Email address

saberipour.b@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-22, 1397/06/31

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cordia Myxa on prevention the effect of mouthwashes fruits of stomatitis (mouth sores) in patients receiving chemotherapy

Public title

Cordia Myxa on prevention the effect of mouthwashes fruits of stomatitis (mouth sores) in patients receiving chemotherapy

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Age over 18 years Acute leukemia under periodic chemotherapy in the induction and intensification phases
 Complete alertness
Exclusion criteria:
 Asthma, allergies, and other sensitivity diseases
 Simultaneous chemotherapy and radiotherapy
 Development of a systemic infection during the study.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Cordia Myxa mouthwash and mouthwash after the approval of the pharmacist and an expert oncology participant in the research were coded without the knowledge of the researcher. After obtaining a license from the University's Ethics Committee and explaining to patients undergoing chemotherapy, they were placed in one of the two intervention and placebo groups. And received one of two types of mouthwash.

Placebo
Used

Assignment
Single

Other design features
The present randomized, double-blind, controlled clinical trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

plain 16-Alley of Arasham-In between the Great and the Masjid-Nazari Pour-Ahwaz

City

Ahvaz

Province

Khouzestan

Postal code

6195734733

Approval date

2018-05-11, 1397/02/21

Ethics committee reference number

IR.Ajums.REC.139.110

Health conditions studied

1

Description of health condition studied

Osteomathite

ICD-10 code

D80-D89

ICD-10 code description

III Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism

Primary outcomes

1

Description

The amount of osteomyte is taken from the WHO standard checklist of osteomathite.

Timepoint

(Before the intervention) , 7 and 14

Method of measurement

The WHO stomatitis checklist, validity and reliability of this checklist has been confirmed.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: On the same day, demographic information of both two groups was recorded and their mouths were examined. Soft toothbrushes were provided to the groups, and correct brushing was taught to them and was exercised, after which, correct use of mouthwash was taught, so that the mouth was washed for one minute with 30 dropsof 5% formulation of lasura (Cordia myxa) fruit mucilage poured in 20 mL water; then the mouthwash was spat out, followed by not eating for up to 1 hour. After training, the treatment.

Category

Prevention

2

Description

Control group: groups were given lasura mouthwash and sterile water (with the same flavor and taste), respectively, in a glass that has a dropper.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa and Baghaee 2 Hospitals

Full name of responsible person

Dr. Bijan Keikhaei Devadzi

Street address

Iran, Ahvaz, Golestan Street

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Khouzestan

Postal code

61335-39345

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+98 61 3336 2414

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itc@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badawi

Street address

Ahvaz Jundishapur University of Medical Sciences,
Ahvaz, Iran

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Email

itc@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Bayan saberipour

Position

Student of Community Health Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Ahvaz Jundishapur University of Medical Sciences,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Shahram Baraz

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data obtained, except for confidential personal information, can be shared

When the data will become available and for how long

2019

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

Noting the source of the use of resources is allowed

From where data/document is obtainable

Saberipour.b@ajums.ac.ir

What processes are involved for a request to access data/document

Submitting a document as a college and academic

Comments